

**REMARKS**

Applicants acknowledge the current status of the claims, as reported in Office Action dated 28 June 2006. Claims 1-17 are pending; and claims 1-17 are subject to restriction and/or election requirement. The Examiner has required restriction to one of two groups under 35 U.S.C. §121 as listed on page 2 of the instant Office Action.

Specifically, the Examiner has restricted the claims of the present application as follows:

- I. Claims 1-14, drawn to a method of treating a TNF $\alpha$  related disorder in a subject comprising administering a human TNF $\alpha$  antibody; classified in Class 424, subclass 145.1.
- II. Claims 15-17, drawn to a kit comprising a human TNF $\alpha$  antibody; classified in Class 530, subclass 388.23.

The Examiner further requires election of species. The asserted species consist of:

- (a) spondyloarthropathy,
- (b) a pulmonary disorder,
- (c) a coronary disorder,
- (d) a metabolic disorder,
- (e) anemia,
- (f) pain,
- (g) a hepatic disorder,
- (h) a skin disorder,
- (i) a nail disorder,
- (j) vasculitis,
- (k) Bechet's disease,
- (l) ankylosing spondylitis,
- (m) asthma,
- (n) chronic obstructive pulmonary disease (COPD),
- (o) idiopathic pulmonary fibrosis (IPF),
- (p) restenosis,
- (q) diabetes,
- (r) anemia,
- (s) pain,
- (t) a Crohn's disease-related disorder,
- (u) juvenile rheumatoid arthritis (JRA),

- (v) a hepatitis C virus infection,
- (w) psoriasis,
- (x) psoriatic arthritis,
- (y) chronic plaque psoriasis,
- (z) age-related cachexia,
- (aa) Alzheimer's disease,
- (bb) brain edema,
- (cc) inflammatory brain injury,
- (dd) chronic fatigue syndrome,
- (ee) dermatomyositis,
- (ff) drug reactions,
- (gg) edema in and/or around the spinal cord,
- (hh) familial periodic fevers,
- (ii) Felty's syndrome,
- (jj) fibrosis,
- (kk) glomerulonephritides (e.g. post-streptococcal glomerulonephritis or IgA nephropathy),
- (ll) loosening of prostheses,
- (mm) microscopic polyangiitis,
- (nn) mixed connective tissue disorder,
- (oo) multiple myeloma,
- (pp) cancer and cachexia,
- (qq) multiple organ disorder,
- (rr) myelo dysplastic syndrome,
- (ss) orchitism osteolysis,
- (tt) pancreatitis, including acute, chronic, and pancreatic abscess,
- (uu) periodontal disease polymyositis,
- (vv) progressive renal failure,
- (ww) pseudogout,
- (xx) pyoderma gangrenosum,
- (yy) relapsing polychondritis,
- (zz) rheumatic heart disease,
- (aaa) sarcoidosis,

- (bbb) sclerosing cholangitis,
- (ccc) stroke,
- (ddd) thoracoabdominal aortic aneurysm repair (TAAA),
- (eee) TNF receptor associated periodic syndrome (TRAPS),
- (fff) symptoms related to Yellow Fever vaccination,
- (ggg) inflammatory diseases associated with the ear, chronic ear inflammation, or pediatric ear inflammation.

Briefly, the reasons for restriction asserted in the Office Action are that Invention I is drawn to a process of use, and Invention II is drawn to a product, which product can be used in a materially different process. Applicants respectfully traverse the restriction of claims, and request reconsideration and withdrawal of restriction requirement.

Proper restriction between independent and distinct inventions claimed in the same application requires that (1) the invention must be independent and distinct as claimed and (2) there must be a serious burden placed on the Examiner by not requiring election. If either criteria are not met, restriction is not proper. The term “independent” means that there is no disclosed relationship between the two or more subjects disclosed in a patent application. The term “distinct”, means two or more subjects as disclosed are related but are capable of separate manufacture, use or sale as claimed, and are patentable over each other. (see M.P.E.P. §802.01). Further, with respect to the burden of the examination, M.P.E.P. §803 states in relevant part, “If the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent and distinct inventions.”

Applicants assert that the claims are drawn to a single inventive concept and a single inventive effort, the search and examination of which would not place a serious burden on the Examiner. The claims are different aspects and embodiments of the same disclosed subject matter.

Applicants’ invention is directed to a method of treating TNF $\alpha$  related disorder in a subject comprising administering to a subject in need, a therapeutically effective amount of a neutralizing, high affinity, TNF $\alpha$  antibody, such that TNF $\alpha$  related disorder is treated. Additional embodiments of the invention include the product, a kit comprising a pharmaceutical composition comprising the TNF $\alpha$  antibody to be administered to a subject being treated for TNF $\alpha$  related disorder. Thus, the method of treating TNF $\alpha$  related disorder in a subject with a therapeutically effective amount of a TNF $\alpha$  antibody, and the kit comprising a pharmaceutical composition comprising the TNF $\alpha$  antibody are both linked. Therefore, the subject matter of Applicants’ Patent application are not “independent” as determined by M.P.E.P. 802.01.

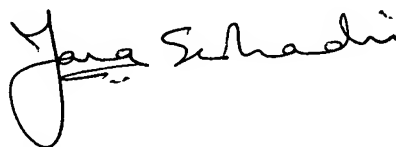
The pharmaceutical composition comprising the TNF $\alpha$  antibody in the kit is to be used to treat TNF $\alpha$  related disorder in the subject. Thus, the method of treating TNF $\alpha$  related disorder in a subject, and the kit comprising a pharmaceutical composition comprising the TNF $\alpha$  antibody represent different embodiments of one invention. Therefore, the subjects disclosed in the instant application do not meet the criteria for "distinct" as defined in M.P.E.P. § 802.01.

The present application contains a single searchable, unifying aspect, i.e. method of treating TNF $\alpha$  related disorder in a subject with a TNF $\alpha$  antibody, and a kit that comprises a TNF $\alpha$  antibody to treat TNF $\alpha$  related disorder in a subject. Therefore, Applicants submit that the Examiner can search and examine the application without serious burden. Thus, Applicants respectfully submit that Applicants' invention does not meet the threshold of "two or more independent and distinct" inventions as required in 35 U.S.C. §121 and as such the restriction requirement is improper. In view of the foregoing, Applicants respectfully request withdrawal of the restriction requirement.

Notwithstanding Applicants' belief that the restriction and requirement of election are improper, and without in any way acquiescing to the reasons for the requirements set forth in the Office Action, but in order to be fully responsive to the Office Action, Applicants provisionally elect for examination the claims of Group I.

As to election of a species, Applicants elect the disclosed species (w) psoriasis. It is Applicants' understanding that the species election is for searching purposes only and, upon a finding of allowability of the elected species, the remaining species also will be searched. Applicants also reserve the right to traverse the restriction between the non-elected groups and species in this or a separate application.

Respectfully submitted,



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